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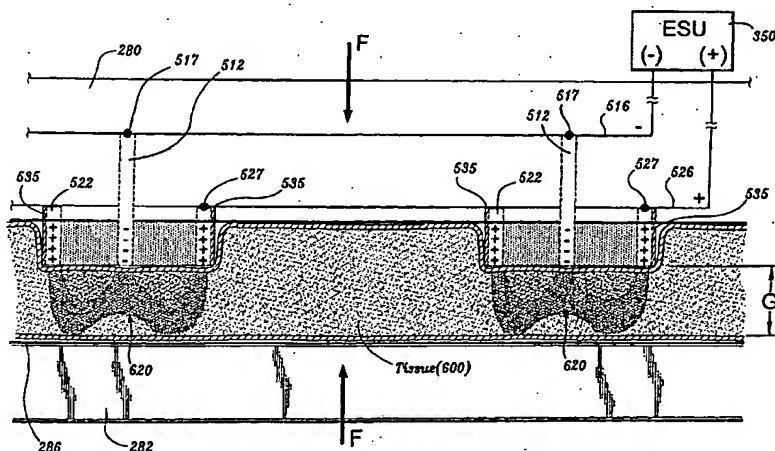
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(54) Title: **BIPOLAR CONCENTRIC ELECTRODE ASSEMBLY FOR SOFT TISSUE FUSION**



(57) Abstract: A bipolar electrosurgical forceps for treating tissue includes a pair of opposing first and second jaw members each having a tissue engaging surface disposed thereon. Each of the jaw members is movable relative to one another from a first position to approximate tissue to a second position for engaging tissue therebetween. The first jaw member includes a plurality of ring electrodes disposed thereon having a first electrical potential and the second jaw member includes a corresponding plurality of post electrodes disposed thereon having a second electrical potential. Each of the plurality of post electrodes is inwardly disposed of a respective ring electrode to form an electrode micro-sealing pad wherein upon activation of the forceps tissue grasped between each electrode micro-sealing pad is sealed while tissue adjacent to each electrode micro-sealing pads remains viable.

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BIPOLAR CONCENTRIC ELECTRODE ASSEMBLY FOR SOFT TISSUE FUSION**BACKGROUND**

The present disclosure relates to forceps used for open and/or endoscopic surgical procedures. More particularly, the present disclosure relates to a forceps which applies a unique combination of mechanical clamping pressure and electrosurgical current to micro-seal soft tissue to promote tissue healing.

Technical Field

A hemostat or forceps is a simple plier-like tool which uses mechanical action between its jaws to constrict vessels and is commonly used in open surgical procedures to grasp, dissect and/or clamp tissue. Electrosurgical forceps utilize both mechanical clamping action and electrical energy to effect hemostasis by heating the tissue and blood vessels to coagulate, cauterize and/or seal tissue. The electrode of each opposing jaw member is charged to a different electric potential such that when the jaw members grasp tissue, electrical energy can be selectively transferred through the tissue. A surgeon can either cauterize, coagulate/desiccate and/or simply reduce or slow bleeding, by controlling the intensity, frequency and duration of the electrosurgical energy applied between the electrodes and through the tissue.

For the purposes herein, the term "cauterization" is defined as the use of heat to destroy tissue (also called "diathermy" or "electrodiathermy"). The term "coagulation" is defined as a process of desiccating tissue wherein the tissue cells are ruptured and dried. "Vessel sealing" is defined as the process of liquefying the collagen, elastin and ground substances in the tissue so that it reforms into a fused mass with significantly-reduced demarcation between the opposing tissue structures (opposing walls of the lumen). Coagulation of small vessels is usually sufficient to permanently close them. Larger vessels or tissue need to be sealed to assure permanent closure.

Commonly-owned U.S. Application Serial Nos. PCT Application Serial No. PCT/US01/11340 filed on April 6, 2001 by Dycus, et al. entitled "VESSEL SEALER AND DIVIDER", U.S. Application Serial No. 10/116,824 filed on April 5, 2002 by Tetzlaff et al. entitled "VESSEL SEALING INSTRUMENT" and PCT Application Serial No. PCT/US01/11420 filed on April 6, 2001 by Tetzlaff et al. entitled "VESSEL SEALING INSTRUMENT" teach that to effectively seal tissue or vessels, especially large vessels, two predominant mechanical parameters must be accurately controlled: 1) the pressure applied to the vessel; and 2) the gap distance between the conductive tissue contacting surfaces (electrodes). As can be appreciated, both of these parameters are affected by the thickness of the vessel or tissue being sealed. Accurate application of pressure is important for several reasons: to oppose the walls of the vessel; to reduce the tissue impedance to a low enough value that allows enough electrosurgical energy through the tissue; to overcome the forces of expansion during tissue heating; and to contribute to the end tissue thickness which is an indication of a good seal. It has been determined

that a typical sealed vessel wall is optimum between 0.001 inches and 0.006 inches. Below this range, the seal may shred or tear and above this range the lumens may not be properly or effectively sealed.

With respect to smaller vessels, the pressure applied become less relevant and the gap distance between the electrically conductive surfaces becomes more significant for effective sealing. In other words, the chances of the two electrically conductive surfaces touching during activation increases as the tissue thickness and the vessels become smaller.

As can be appreciated, when cauterizing, coagulating or sealing vessels, the tissue disposed between the two opposing jaw members is essentially destroyed (e.g., heated, ruptured and/or dried with cauterization and coagulation and fused into a single mass with vessel sealing). Other known electrosurgical instruments include blade members or shearing members which simply cut tissue in a mechanical and/or electromechanical manner and, as such, also destroy tissue viability.

When trying to electrosurgically treat large, soft tissues (e.g., lung, intestine, lymph ducts, etc.) to promote healing, the above-identified surgical treatments are generally impractical due to the fact that in each instance the tissue or a significant portion thereof is essentially destroyed to create the desired surgical effect, cauterization, coagulation and/or sealing. As a result thereof, the tissue is

no longer viable across the treatment site, i.e., there remains no feasible path across the tissue for vascularization.

Thus, a need exists to develop an electrosurgical forceps which effectively treats tissue while maintaining tissue viability across the treatment area to promote tissue healing.

SUMMARY

The present disclosure relates to a bipolar electrosurgical forceps for treating tissue and includes a pair of opposing first and second jaw members each having a tissue engaging surface disposed thereon. The opposing jaw members are movable relative to one another from a first position to approximate tissue to a second position for engaging tissue between the jaw members. At least one of the first and second jaw members includes a plurality of ring-like electrodes disposed thereon having a first electrical potential and at least one of the first and second jaw members includes a corresponding plurality of post electrodes disposed thereon having a second electrical potential. Each of the plurality of post electrodes is concentrically and inwardly disposed of a respective ring electrode to form an electrode micro-sealing pad. Upon activation of the forceps, tissue grasped between the each of the plurality of electrode micro-sealing pads of the jaw members is sealed while tissue adjacent to each of the electrode micro-sealing pads remains viable.

In one embodiment, the ring electrode are disposed on one of the first and second jaw members and the post electrodes are disposed on the other of the first and second jaw members. Alternatively, the ring electrodes and the post electrodes are disposed on the same jaw member. An electrically insulative material is disposed between each ring electrode and the corresponding post electrode of each electrode micro-sealing pad. Preferably, the electrode micro-sealing pads are arranged in a pattern-like manner across and/or along the jaw members.

In another embodiment, the forceps includes a ratchet or handle mechanism which provides a closure pressure in the range of about 3 kg/cm² to about 16 kg/cm² between opposing jaw members distributed over tissue contact surfaces. At least one non-conductive stop member may be disposed on one or both jaw members to control the distance between opposing jaw members when tissue is held therebetween. Preferably, at least one of the jaw members includes a non-stick coating disposed on the tissue engaging surfaces of each electrode micro-sealing pad and/or other tissue engaging surfaces of the jaw members. Preferably, the non-stick coating includes one or a combination of one or more of the following materials: TiN, ZrN, TiAlN, CrN, nickel/chrome alloys with a Ni/Cr ratio of approximately 5:1, Inconel 600, Ni200 and Ni201.

In yet another embodiment, each of the electrodes micro-sealing pads is separated by a distance in the range of about 0.020 inches to about 0.2

inches from any adjacent pad. The electrode micro-sealing pads may be flush with the non-conductive tissue engaging surfaces of the jaw members and a series of stop members regulate the distance between opposing jaw members. Alternatively, the electrode micro-sealing pads may protrude from about 0.001 inches to about 0.2 inches from one of the first and second jaw members and regulate the distance between the jaw members for effective micro-sealing.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the subject instrument are described herein with reference to the drawings wherein:

Fig. 1A is a perspective view of an endoscopic forceps having an electrode assembly in accordance with the present disclosure;

Fig. 1B is a perspective view of an open forceps having a electrode assembly in accordance with the present disclosure;

Fig. 2 is an enlarged, perspective view of the electrode assembly of the forceps of Fig. 1B shown in an open configuration;

Fig. 3A is an enlarged, schematic view of one embodiment of the electrode assembly showing a pair of opposing, concentrically-oriented electrodes disposed on a pair of opposing jaw members;

Fig. 3B is a partial, side cross-sectional view of the electrode assembly of Fig. 3A;

Fig. 4A is an enlarged, schematic view of another embodiment of the electrode assembly showing a plurality of concentrically-oriented electrode micro-sealing pads disposed on the same jaw member;

Fig. 4B is a greatly enlarged view of the area of detail in Fig. 4A showing the electrical path during activation of the electrode assembly;

Fig. 4C is an enlarged schematic view showing the individual micro-sealing sites and viable tissue areas between the two jaw members after activation;

Fig. 5A is a schematic, perspective view of the jaw members approximating tissue;

Fig. 5B is a schematic, perspective view of the jaw members grasping tissue; and

Fig. 5C is a schematic, perspective view showing a series of micro-seals disposed in a pattern across the tissue after activation of the electrode assembly.

DETAILED DESCRIPTION

Referring now to Fig. 1A, a bipolar forceps 10 is shown for use with various surgical procedures. Forceps 10 generally includes a housing 20, a handle assembly 30, a rotating assembly 80, an activation assembly 70 and an electrode assembly 110 which mutually cooperate to grasp and seal tissue 600 (See Figs. 5A-5C). Although the majority of the figure drawings depict a bipolar forceps 10 for use in connection with endoscopic surgical procedures, an open forceps 200 is also contemplated for use in connection with traditional open surgical procedures and is shown by way of example in Fig. 1B and is described below. For the purposes herein, either an endoscopic instrument or an open instrument may be utilized with the electrode assembly described herein. Obviously, different electrical and mechanical connections and considerations apply to each particular type of instrument, however, the novel aspects with respect to the electrode assembly and its operating characteristics remain generally consistent with respect to both the open or endoscopic designs.

More particularly, forceps 10 includes a shaft 12 which has a distal end 14 dimensioned to mechanically engage a jaw assembly 110 and a proximal

end 16 which mechanically engages the housing 20. The shaft 12 may be bifurcated at the distal end 14 thereof to receive the jaw assembly 110. The proximal end 16 of shaft 12 mechanically engages the rotating assembly 80 to facilitate rotation of the jaw assembly 110. In the drawings and in the descriptions which follow, the term "proximal", as is traditional, will refer to the end of the forceps 10 which is closer to the user, while the term "distal" will refer to the end which is further from the user.

Forceps 10 also includes an electrical interface or plug 300 which connects the forceps 10 to a source of electrosurgical energy, e.g., an electrosurgical generator 350 (See Fig. 3B). Plug 300 includes a pair of prong members 302a and 302b which are dimensioned to mechanically and electrically connect the forceps 10 to the electrosurgical generator 350. An electrical cable 310 extends from the plug 300 to a sleeve 99 which securely connects the cable 310 to the forceps 10. Cable 310 is internally divided within the housing 20 to transmit electrosurgical energy through various electrical feed paths to the jaw assembly 110 as explained in more detail below.

Handle assembly 30 includes a fixed handle 50 and a movable handle 40. Fixed handle 50 is integrally associated with housing 20 and handle 40 is movable relative to fixed handle 50 to actuate a pair of opposing jaw members 280 and 282 of the jaw assembly 110 as explained in more detail below. The activation assembly 70 is selectively movable by the surgeon to energize the jaw assembly 110. Movable handle 40 and activation assembly 70 are preferably of unitary construction and are operatively connected to the housing 20 and the fixed handle 50 during the assembly process.

As mentioned above, jaw assembly 110 is attached to the distal end 14 of shaft 12 and includes a pair of opposing jaw members 280 and 282. Movable handle 40 of handle assembly 30 imparts movement of the jaw members 280 and 282 from an open position wherein the jaw members 280 and 282 are disposed in spaced relation relative to one another for approximating tissue 600, to a clamping or closed position wherein the jaw members 280 and 282 cooperate to grasp tissue 600 therebetween (See Figs. 5A-5C).

It is envisioned that the forceps 10 may be designed such that it is fully or partially disposable depending upon a particular purpose or to achieve a particular result. For example, jaw assembly 110 may be selectively and releasably engageable with the distal end 14 of the shaft 12 and/or the proximal end 16 of shaft 12 may be selectively and releasably engageable with the housing 20 and the handle assembly 30. In either of these two instances, the forceps 10 would be considered "partially disposable" or "reposable", i.e., a new or different jaw assembly 110 (or jaw assembly 110 and shaft 12) selectively replaces the old jaw assembly 110 as needed.

Referring now to Figs. 1B and 2, an open forceps 200 includes a pair of elongated shaft portions 212a each having a proximal end 216a and 216b, respectively, and a distal end 214a and 214b, respectively. The forceps 200 includes jaw assembly 210 which attaches to distal ends 214a and 214b of shafts

212a and 212b, respectively. Jaw assembly 210 includes opposing jaw members 280 and 282 which are pivotably connected about a pivot pin 219.

Preferably, each shaft 212a and 212b includes a handle 217a and 217b disposed at the proximal end 216a and 216b thereof which each define a finger hole 218a and 218b, respectively, therethrough for receiving a finger of the user. As can be appreciated, finger holes 218a and 218b facilitate movement of the shafts 212a and 212b relative to one another which, in turn, pivot the jaw members 280 and 282 from an open position wherein the jaw members 280 and 282 are disposed in spaced relation relative to one another for approximating tissue 600 to a clamping or closed position wherein the jaw members 280 and 282 cooperate to grasp tissue 600 therebetween. A ratchet 230 is preferably included for selectively locking the jaw members 280 and 282 relative to one another at various positions during pivoting.

Preferably, each position associated with the cooperating ratchet interfaces 230 holds a specific, i.e., constant, strain energy in the shaft members 212a and 212b which, in turn, transmits a specific closing force to the jaw members 280 and 282. It is envisioned that the ratchet 230 may include graduations or other visual markings which enable the user to easily and quickly ascertain and control the amount of closure force desired between the jaw members 280 and 282.

One of the shafts, e.g., 212b, includes a proximal shaft connector /flange 221 which is designed to connect the forceps 200 to a source of electrosurgical energy such as an electrosurgical generator 350 (Fig. 3B). More particularly, flange 221 mechanically secures electrosurgical cable 310 to the forceps 200 such that the user may selectively apply electrosurgical energy as needed. The proximal end of the cable 310 includes a similar plug 300 as described above with respect to Fig. 1A. The interior of cable 310 houses a pair of leads which conduct different electrical potentials from the electrosurgical generator 350 to the jaw members 280 and 282 as explained below with respect to Fig. 2.

Preferably, the jaw members 280 and 282 are generally symmetrical and include similar component features which cooperate to permit facile rotation about pivot 219 to effect the grasping of tissue 600. Each jaw member 280 and 282 includes a non-conductive tissue contacting surface 284 and 286, respectively, which cooperate to engage the tissue 600 during treatment.

As best shown in Fig. 2, the various electrical connections of the electrode assembly 210 are preferably configured to provide electrical continuity to an array of electrode micro-sealing pads 500 disposed across one or both jaw members 280 and 282. The electrical paths 416, 426 or 516, 526 from the array of electrode micro-sealing pads 500 are preferably mechanically and electrically interfaced with corresponding electrical connections (not shown) disposed within shafts 212a and 212b, respectively. As can be appreciated, these electrical paths

416, 426 or 516, 526 may be permanently soldered to the shafts 212a and 212b during the assembly process of a disposable instrument or, alternatively, selectively removable for use with a reusable instrument.

As best shown in Figs. 4A-4C, the electrical paths are connected to the plurality of electrode micro-sealing pads 500 within the jaw assembly 210. More particularly, the first electrical path 526 (i.e., an electrical path having a first electrical potential) is connected to each ring electrode 522 of each electrode micro-sealing pad 500. The second electrical path 516 (i.e., an electrical path having a second electrical potential) is connected to each post electrode 522 of each electrode micro-sealing pad 500.

Preferably, the electrical paths 516 and 526 do not encumber the movement of the jaw members 280 and 282 relative to one another during the manipulation and grasping of tissue 400. Likewise, the movement of the jaw members 280 and 282 do not unnecessarily strain the electrical paths 516 and 526 or their respective connections 517, 527.

As best seen in Figs. 2-5C, jaw members 280 and 282 both include non-conductive tissue contacting surfaces 284 and 286, respectively, disposed along substantially the entire longitudinal length thereof (i.e., extending substantially from the proximal to distal end of each respective jaw member 280 and 284). Preferably, the non-conductive tissue contacting surfaces 284 and 286

are made from an insulative material such as ceramic due to its hardness and inherent ability to withstand high temperature fluctuations. Alternatively, the non-conductive tissue contacting surfaces 284 and 286 may be made from a material or a combination of materials having a high Comparative Tracking Index (CTI) in the range of about 300 to about 600 volts. Examples of high CTI materials include nylons and syndiotactic polystyrenes such as QUESTRA[®] manufactured by DOW Chemical. Other materials may also be utilized either alone or in combination, e.g., Nylons, Syndiotactic-polystyrene (SPS), Polybutylene Terephthalate (PBT), Polycarbonate (PC), Acrylonitrile Butadiene Styrene (ABS), Polyphthalamide (PPA), Polyimide, Polyethylene Terephthalate (PET), Polyamide-imide (PAI), Acrylic (PMMA), Polystyrene (PS and HIPS), Polyether Sulfone (PES), Aliphatic Polyketone, Acetal (POM) Copolymer, Polyurethane (PU and TPU), Nylon with Polyphenylene-oxide dispersion and Acrylonitrile Styrene Acrylate. Preferably, the non-conductive tissue contacting surfaces 284 and 286 are dimensioned to securingly engage and grasp the tissue 600 and may include serrations (not shown) or roughened surfaces to facilitate approximating and grasping tissue.

It is envisioned that one of the jaw members, e.g., 282, includes at least one stop member 235a, 235b (Fig. 2) disposed on the inner facing surface of the sealing surfaces 286. Alternatively or in addition, one or more stop members 235a, 235b may be positioned adjacent to the non-conductive sealing surfaces 284, 286 or proximate the pivot 219. The stop members 235a, 235b are preferably designed to define a gap "G" (Fig. 5B) between opposing jaw members 280 and

282 during the micro-sealing process. Preferably the separation distance during micro-sealing or the gap distance "G" is within the range of about 0.001 inches (~0.03 millimeters) to about 0.006 inches (~0.016 millimeters). One or more stop members 235a, 235b may be positioned on the distal end and proximal end of one or both of the jaw members 280, 282 or may be positioned between adjacent electrode micro-sealing pads 500. Moreover, the stop members 235a and 235b may be integrally associated with the non-conductive tissue contacting surfaces 284 and 286. It is envisioned that the array of electrode micro-sealing pads 500 may also act as stop members for regulating the distance "G" between opposing jaw members 280, 282 (See Fig. 4C).

As mentioned above, the effectiveness of the resulting micro-seal is dependent upon the pressure applied between opposing jaw members 280 and 282, the pressure applied by each electrode micro-sealing pad 500 at each micro-sealing site 620 (Fig. 4C), the gap "G" between the opposing jaw members 280 and 282 (either regulated by a stop member 235a, 235b or the array of electrode micro-sealing pads 500) and the control of the electrosurgical intensity during the micro-sealing process. Applying the correct force is important to oppose the walls of the tissue; to reduce the tissue impedance to a low enough value that allows enough current through the tissue; and to overcome the forces of expansion during tissue heating in addition to contributing towards creating the required end tissue thickness which is an indication of a good micro-seal. Regulating the gap distance

and regulating the electrosurgical intensity ensure a consistent seal quality and reduce the likelihood of collateral damage to surrounding tissue.

As best show in Fig. 2, the electrode micro-sealing pads 500 are arranged in a longitudinal, pair-like fashion along the tissue contacting surfaces 286 and/or 284. Preferably, two or more micro-sealing pads 500 may extend transversally across the tissue contacting surface 286. Figs. 3A and 3B show one embodiment of the present disclosure wherein the electrode micro-sealing pads 500 include a ring electrode 422 disposed on one jaw members 282 and a post electrode 412 disposed on the other jaw member 280. The ring electrode 422 includes an insulating material 424 disposed therein to form a ring electrode and insulator assembly 420 and the post electrode 422 includes an insulating material disposed therearound to form a post electrode and insulator assembly 430. Each post electrode assembly 430 and the ring electrode assembly 420 of this embodiment together define one electrode micro-sealing pad 400. Although shown as a circular-shape, ring electrode 422 may assume any other annular or enclosed configuration or alternatively partially enclosed configuration such as a C-shape arrangement.

As best shown in Fig. 3B, the post electrode 422 is concentrically centered opposite the ring electrode 422 such that when the jaw members 280 and 282 are closed about the tissue 600, electrosurgical energy flows from the ring electrode 422, through tissue 600 and to the post electrode 412. The insulating

materials 414 and 424 isolate the electrodes 412 and 422 and prevent stray current tracking to surrounding tissue. Alternatively, the electrosurgical energy may flow from the post electrode 412 to the ring electrode 422 depending upon a particular purpose.

Figs. 4A-4C show an alternate embodiment of the jaw assembly 210 according to the present disclosure for micro-sealing tissue 600 wherein each electrode micro-sealing pad 500 is disposed on a single jaw member, e.g., jaw member 280. More particularly and as best illustrated in Fig. 4B, each electrode micro-sealing pad 500 consists of an inner post electrode 512 which is surrounded by an insulative material 514, e.g., ceramic. The insulative material 514 is, in turn, encapsulated by a ring electrode 522. Preferably, a second insulative material 535 (or the same insulative material 514) encases the ring electrode 522 to prevent stray electrical currents to surrounding tissue.

The ring electrode 522 is connected to the electrosurgical generator 350 by way of a cable 526 (or other conductive path) which transmits a first electrical potential to each ring electrode 522 at connection 527. The post electrode 512 is connected to the electrosurgical generator 350 by way of a cable 516 (or other conductive path) which transmits a second electrical potential to each post electrode 522 at connection 517. A controller 375 (See Fig. 4B) may be electrically interposed between the generator 350 and the electrodes 512, 522 to regulate the electrosurgical energy supplied thereto depending upon certain

electrical parameters, current impedance, temperature, voltage, etc. For example, the instrument or the controller may include one or more smart sensors (not shown) which communicate with the electrosurgical generator 350 (or smart circuit, computer, feedback loop, etc.) to automatically regulate the electrosurgical intensity (waveform, current, voltage, etc.) to enhance the micro-sealing process. The sensor may measure or monitor one or more of the following parameters: tissue temperature, tissue impedance at the micro-seal, change in impedance of the tissue over time and/or changes in the power or current applied to the tissue over time. An audible or visual feedback monitor (not shown) may be employed to convey information to the surgeon regarding the overall micro-seal quality or the completion of an effective tissue micro-seal.

Moreover, a PCB circuit or flex circuit (not shown) may be utilized to provide information relating to the gap distance (e.g., a proximity detector may be employed) between the two jaw members 280 and 282, the micro-sealing pressure between the jaw members 280 and 282 prior to and during activation, load (e.g., strain gauge may be employed), the tissue thickness prior to or during activation, the impedance across the tissue during activation, the temperature during activation, the rate of tissue expansion during activation and micro-sealing. It is envisioned that the PCB circuit may be designed to provide electrical feedback to the generator 350 relating to one or more of the above parameters either on a continuous basis or upon inquiry from the generator 350. For example, a PCB circuit may be employed to control the power, current and/or type of current

waveform from the generator 350 to the jaw members 280, 282 to reduce collateral damage to surrounding tissue during activation, e.g., thermal spread, tissue vaporization and/or steam from the treatment site. Examples of a various control circuits, generators and algorithms which may be utilized are disclosed in U.S. Patent No 6,228,080 and U.S. Application Serial No. 10/073,761 the entire contents of both of which are hereby incorporated by reference herein.

In use as depicted in Figs. 5A-5C, the surgeon initially approximates the tissue (Fig. 5A) between the opposing jaw member 280 and 282 and then grasps the tissue 600 (Fig. 5B) by actuating the jaw members 280, 282 to rotate about pivot 219. Once the tissue is grasped, the surgeon selectively activates the generator 350 to supply electrosurgical energy to the array of the electrode micro-sealing pads 500. More particularly, electrosurgical energy flows from the ring electrode 522, through the tissue 600 and to the post electrode 512 (See Figs. 4B and 4C). As a result thereof, an intermittent pattern of individual micro-seals 630 is created along and across the tissue 600 (See Fig. 5C). The arrangement of the micro-sealing pads 500 across the tissue only seals the tissue which is between each micro-sealing pad 500 and the opposing jaw member 282. The adjacent tissue remains viable which, as can be appreciated, allows blood and nutrients to flow through the sealing site 620 and between the individual micro-seals 630 to promote tissue healing and reduce the chances of tissue necrosis. By selectively regulating the closure pressure "F", gap distance "G", and electrosurgical intensity,

effective and consistent micro-seals 630 may be created for many different tissue types.

It is further envisioned that selective ring electrodes and post electrodes may have varying electric potentials upon activation. For example, at or proximate the distal tip of one of the jaw members, one or a series of electrodes may be electrically connected to a first potential and the corresponding electrodes (either on the same jaw or perhaps the opposing jaw) may be connected to a second potential. Towards the proximal end of the jaw member, one or a series of electrodes may be connected to a third potential and the corresponding electrodes connected to yet a fourth potential. As can be appreciated, this would allow different types of tissue sealing to take place at different portions of the jaw members upon activation. For example, the type of sealing could be based upon the type of tissues involved or perhaps the thickness of the tissue. To seal larger tissue, the user would grasp the tissue more towards the proximal portion of the opposing jaw members and to seal smaller tissue, the user would grasp the tissue more towards the distal portion of the jaw members. It is also envisioned that the pattern and/or density of the micro-sealing pads may be configured to seal different types of tissue or thicknesses of tissue along the same jaw members depending upon where the tissue is grasped between opposing jaw members.

From the foregoing and with reference to the various figure drawings, those skilled in the art will appreciate that certain modifications can also be made

to the present disclosure without departing from the scope of the same. For example, it is envisioned that by making the forceps 100, 200 disposable, the forceps 100, 200 is less likely to become damaged since it is only intended for a single use and, therefore, does not require cleaning or sterilization. As a result, the functionality and consistency of the vital micro-sealing components, e.g., the conductive micro-sealing electrode pads 500, the stop member(s) 235a, 235b, and the insulative materials 514, 535 will assure a uniform and quality seal.

Experimental results suggest that the magnitude of pressure exerted on the tissue by the micro-sealing pads 112 and 122 is important in assuring a proper surgical outcome, maintaining tissue viability. Tissue pressures within a working range of about 3 kg/cm² to about 16 kg/cm² and, preferably, within a working range of 7 kg/cm² to 13 kg/cm² have been shown to be effective for micro-sealing various tissue types and vascular bundles.

In one embodiment, the shafts 212a and 212b are manufactured such that the spring constant of the shafts 212a and 212b, in conjunction with the placement of the interfacing surfaces of the ratchet 230, will yield pressures within the above working range. In addition, the successive positions of the ratchet interfaces increase the pressure between opposing micro-sealing surfaces incrementally within the above working range.

It is envisioned that the outer surface of the jaw members 280 and 282 may include a nickel-based material or coating which is designed to reduce adhesion between the jaw members 280, 282 (or components thereof) with the surrounding tissue during activation and micro-sealing. Moreover, it is also contemplated that other components such as the shaft portions 212a, 212b and the rings 217a, 217b may also be coated with the same or a different "non-stick" material. Preferably, the non-stick materials are of a class of materials that provide a smooth surface to prevent mechanical tooth adhesions.

It is also contemplated that the tissue contacting portions of the electrodes and other portions of the micro-sealing pads 400, 500 may also be made from or coated with non-stick materials. When utilized on these tissue contacting surfaces, the non-stick materials provide an optimal surface energy for eliminating sticking due in part to surface texture and susceptibility to surface breakdown due electrical effects and corrosion in the presence of biologic tissues. It is envisioned that these materials exhibit superior non-stick qualities over stainless steel and should be utilized in areas where the exposure to pressure and electrosurgical energy can create localized "hot spots" more susceptible to tissue adhesion. As can be appreciated, reducing the amount that the tissue "sticks" during micro-sealing improves the overall efficacy of the instrument.

The non-stick materials may be manufactured from one (or a combination of one or more) of the following "non-stick" materials: nickel-chrome, chromium nitride, MedCoat 2000 manufactured by The Electrolyzing Corporation of OHIO, Inconel 600 and tin-nickel. Inconel 600 coating is a so-called "super alloy" which is manufactured by Special Metals, Inc. located in Conroe Texas. The alloy is primarily used in environments which require resistance to corrosion and heat. The high Nickel content of Inconel 600 makes the material especially resistant to organic corrosion. As can be appreciated, these properties are desirable for bipolar electrosurgical instruments which are naturally exposed to high temperatures, high RF energy and organic matter. Moreover, the resistivity of Inconel 600 is typically higher than the base electrode material which further enhances desiccation and micro-seal quality.

One particular class of materials disclosed herein has demonstrated superior non-stick properties and, in some instances, superior micro-seal quality. For example, nitride coatings which include, but are not limited to: TiN, ZrN, TiAlN, and CrN are preferred materials used for non-stick purposes. CrN has been found to be particularly useful for non-stick purposes due to its overall surface properties and optimal performance. Other classes of materials have also been found to reducing overall sticking. For example, high nickel/chrome alloys with a Ni/Cr ratio of approximately 5:1 have been found to significantly reduce sticking in bipolar instrumentation.

It is also envisioned that the micro-sealing pads 400, 500 may be arranged in many different configurations across or along the jaw members 280, 282 depending upon a particular purpose. Moreover, it is also contemplated that a knife or cutting element (not shown) may be employed to sever the tissue 600 between a series of micro-sealing pads 400, 500 depending upon a particular purpose. The cutting element may include a cutting edge to simply mechanically cut tissue 600 and/or may be configured to electrosurgically cut tissue 600.

While several embodiments of the disclosure have been shown in the drawings, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED IS:

1. A bipolar electrosurgical forceps, comprising:

first and second opposing jaw members having respective tissue engaging surfaces associated therewith, said first and second jaw members adapted for relative movement between an open position to receive tissue and a closed position engaging tissue between said tissue engaging surfaces; and

at least one of said first and second jaw members including a substantially annular electrode mounted to said tissue engaging surface thereof, at least one of said first and second jaw members including a corresponding post electrode mounted to said tissue engaging surface thereof, said post electrode being in inwardly disposed relation to said annular electrode when said jaw members are in at least said closed position to thereby define a micro-sealing pad whereby, upon energization, electrosurgical energy communicates between said ring electrode and said annular electrode of said micro-sealing pad to thermally treat tissue disposed therebetween.

2. A bipolar electrosurgical forceps according to claim 1 including a plurality of annular electrodes and a plurality of corresponding post electrodes arranged to define a plurality of micro-sealing pads.

3. A bipolar electrosurgical forceps according to claim 2 wherein said micro-sealing pads are arranged in a predetermined pattern along said first and second jaw members.
4. A bipolar electrosurgical forceps according to claim 3 wherein said micro-sealing are arranged in predetermined spaced relation along said first and second jaw members whereby upon energization tissue extending between adjacent micro-sealing pads remains substantially viable.
5. A bipolar electrosurgical forceps according to claim 4 wherein each micro-sealing pad is encapsulated by an electrically insulative material.
6. A bipolar electrosurgical forceps according to claim 1 wherein said annular electrode is disposed on said first jaw member and said post electrode is disposed on said second jaw member.
7. A bipolar electrosurgical forceps according to claim 1 wherein said annular electrode and said post electrode are disposed on said first jaw member.
8. A bipolar electrosurgical forceps according to claim 7 wherein an electrically insulative material is disposed between said ring electrode and said post electrode.

9. A bipolar electrosurgical forceps according to claim 1 further comprising means for providing a closure pressure in the range of about 3 kg/cm² to about 16 kg/cm² between opposing jaw members.
10. A bipolar electrosurgical forceps according to claim 1 wherein at least one of said first and second jaw members includes at least one non-conductive stop member disposed thereon to control the distance between said first and second jaw members when in said closed position thereof.
11. A bipolar electrosurgical forceps according to claim 4 wherein each of said electrode micro-sealing pads is separated from an adjacent electrode micro-sealing pad by a distance in the range of about 0.020 inches to about 0.2 inches.
12. A bipolar electrosurgical forceps according to claim 1 wherein at least one of said first and second jaw members includes a non-stick coating disposed on said tissue engaging surface of each electrode micro-sealing pad.
13. A bipolar electrosurgical forceps according to claim 12 wherein the non-stick coating includes one of: TiN, ZrN, TiAlN, CrN, nickel/chrome alloys with a Ni/Cr ratio of approximately 5:1, Inconel 600, Ni200 and Ni201.
14. A bipolar electrosurgical forceps according to claim 1 wherein said micro-sealing pad is dimensioned to protrude from one of said first and second jaw

members to regulate the distance between said first and second jaw members when in said closed position.

15. A bipolar electrosurgical forceps according to claim 14 wherein said micro-sealing pad is dimensioned to protrude a distance "A" from one of said first and second jaw members, wherein the distance "A" is in the range of about 0.001 inches to about 0.2 inches.

16. A bipolar electrosurgical forceps, comprising:

first and second opposing jaw members each having a tissue engaging surface disposed thereon, said opposing jaw members being movable relative to one another from a first position to approximate tissue to a second position for engaging tissue therebetween;

at least one of said first and second jaw members including a plurality of ring electrodes disposed thereon having a first electrical potential and at least one of the first and second jaw members having a corresponding plurality of post electrodes disposed thereon having a second electrical potential wherein each of said plurality of post electrodes is inwardly disposed of a respective ring electrode to form an electrode micro-sealing pad;

such that upon activation of the forceps the amount of electrosurgical energy between each of said ring and post electrodes pairs is sufficient to seal tissue disposed therebetween while the amount of electrosurgical energy between adjacent electrode micro-sealing pads is substantially less such that the tissue

disposed between adjacent electrode micro-sealing pads remains substantially viable after activation.

17. A bipolar electrosurgical forceps according to claim 16 wherein said ring electrode is disposed on one of said first and second jaw members and said post electrode is disposed on the other of said first and second jaw members.

18. A bipolar electrosurgical forceps according to claim 16 wherein said ring electrode and said post electrode are disposed on the same jaw member.

19. A bipolar electrosurgical forceps according to claim 18 wherein an electrically insulative material is disposed between the ring electrode and post electrode of each electrode micro-sealing pad.

20. A bipolar electrosurgical forceps according to claim 16 wherein said electrode micro-sealing pads are arranged in a pattern-like manner across said jaw members.

21. A bipolar electrosurgical forceps according to claim 16 further comprising means for providing a closure pressure in the range of about 3 kg/cm² to about 16 kg/cm² between opposing jaw members.

22. A bipolar electrosurgical forceps according to claim 16 wherein at least one of the jaw members includes at least one non-conductive stop member disposed thereon to control the distance between opposing jaw members when tissue is held therebetween.

23. A bipolar electrosurgical forceps according to claim 16 wherein each of said electrode micro-sealing pads is separated from an adjacent electrode micro-sealing pad by a distance in the range of about 0.020 inches to about 0.2 inches.

24. A bipolar electrosurgical forceps according to claim 16 wherein the electrode micro-sealing pads protrude from one of the first and second jaw members to regulate the distance between jaw members.

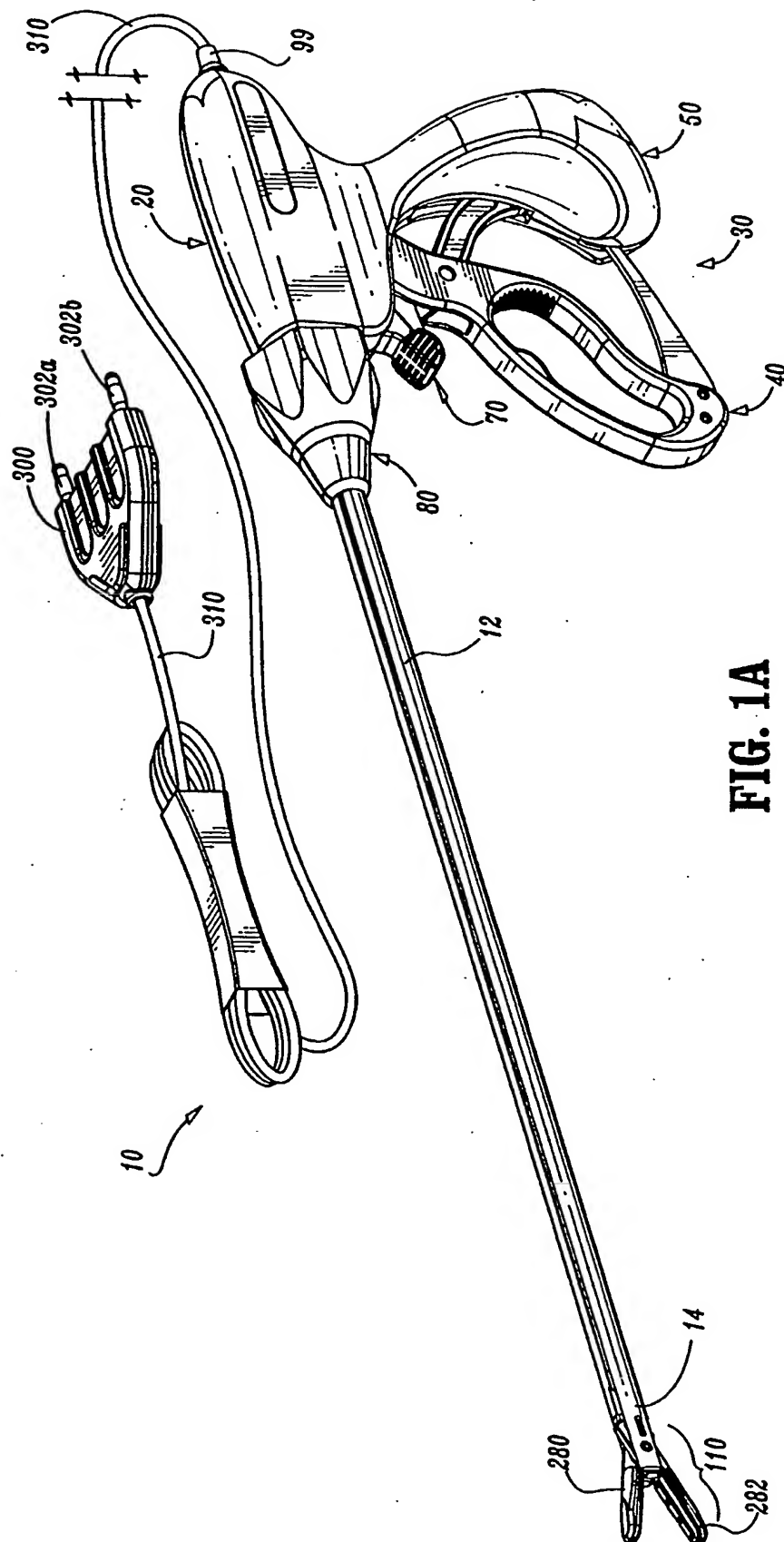


FIG. 1A

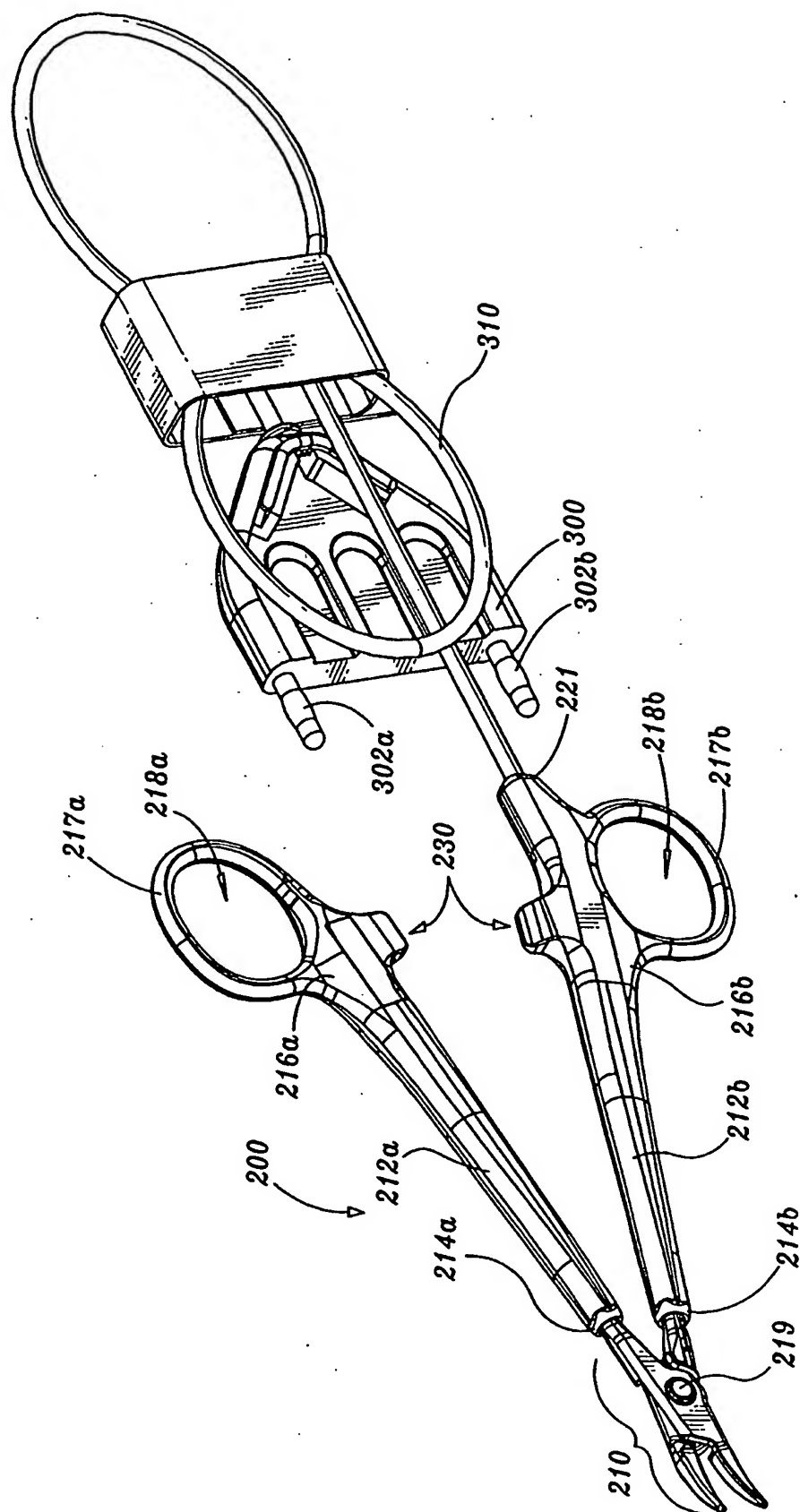
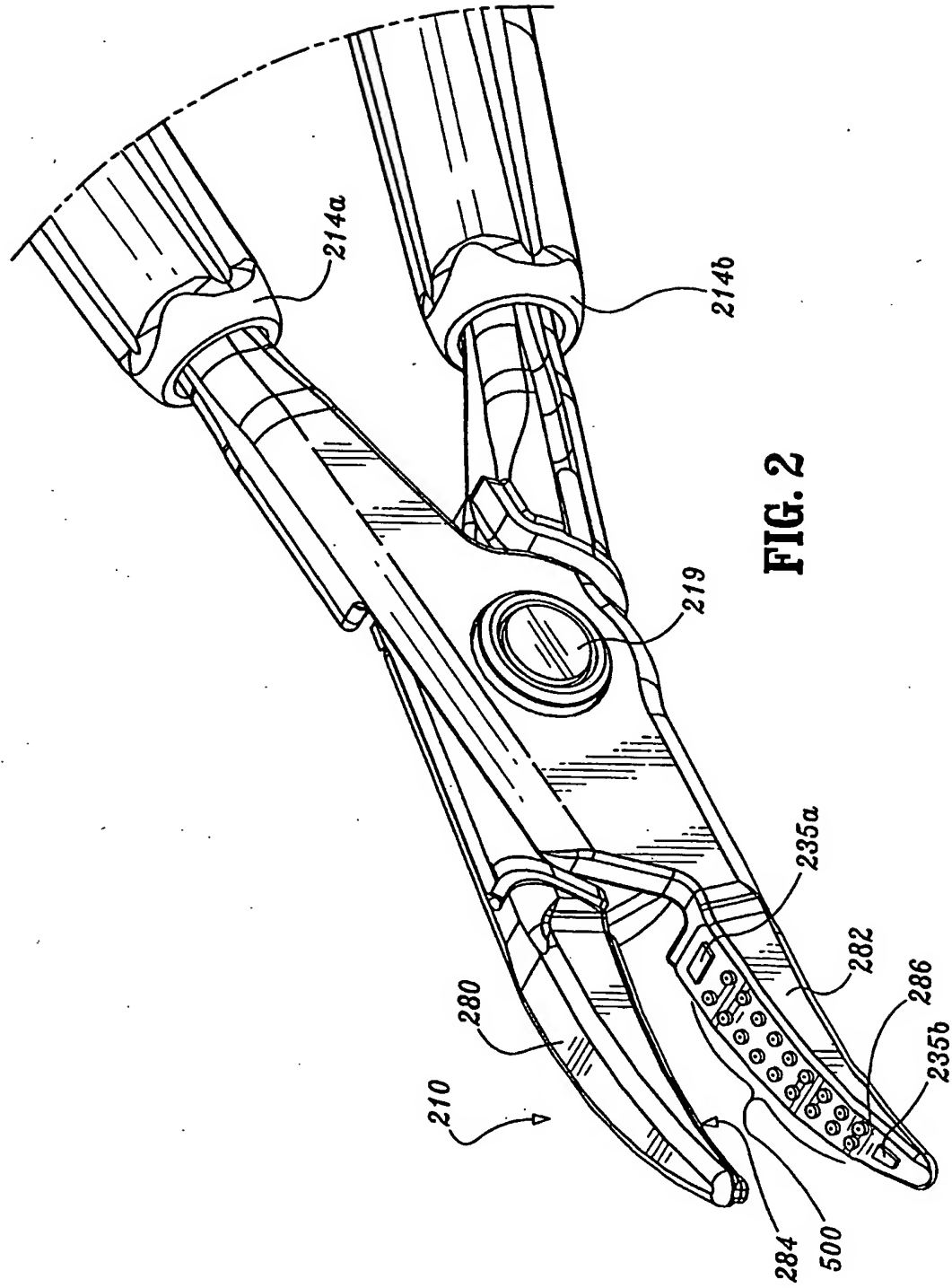
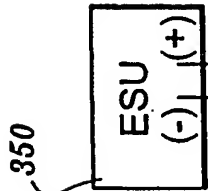
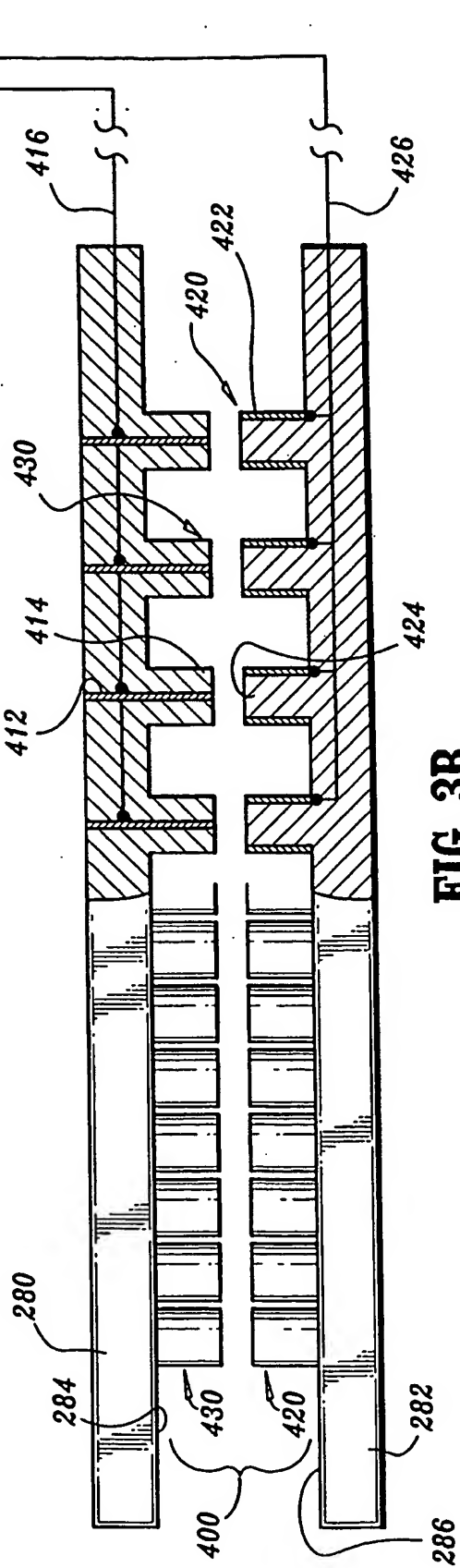
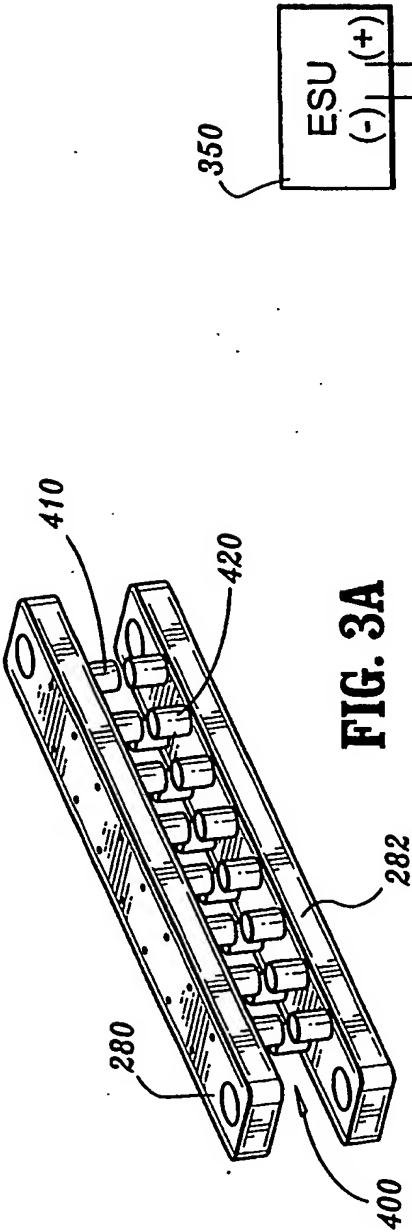


FIG. 1B





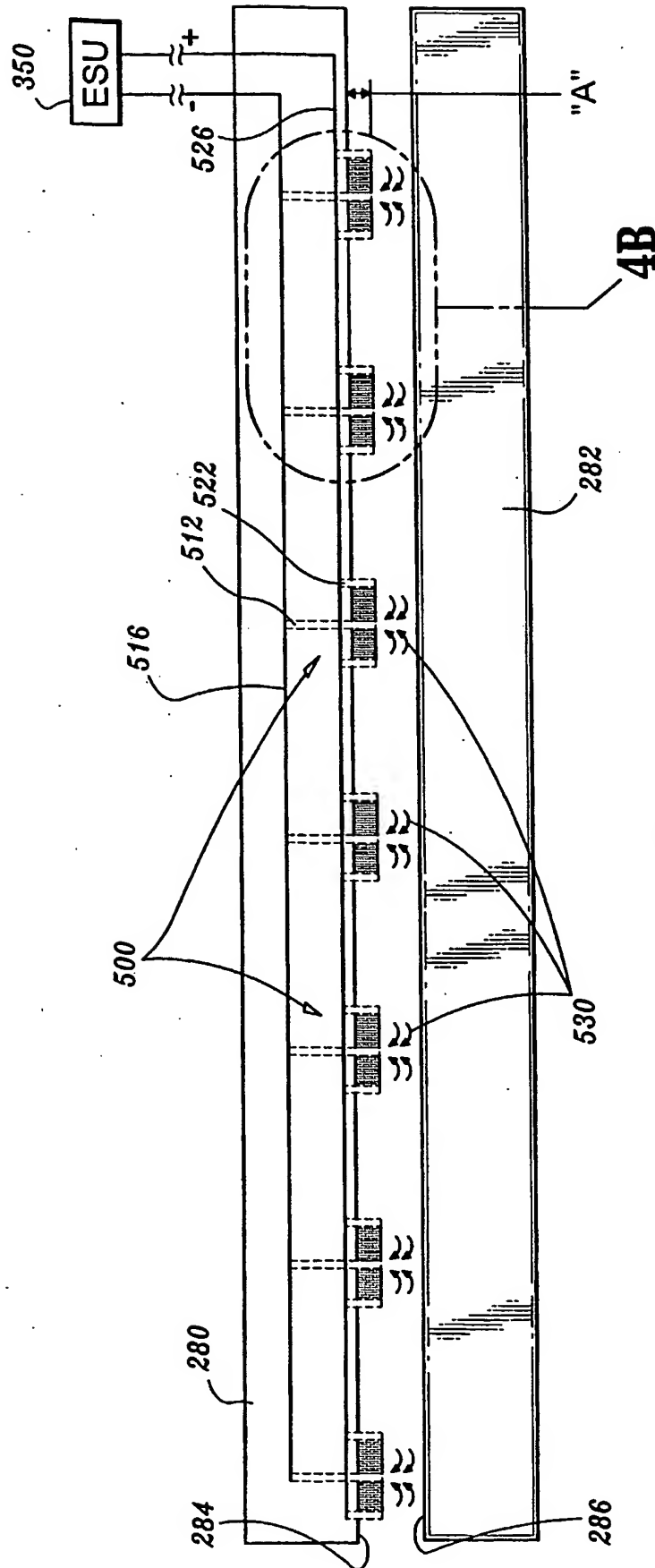


FIG. 4A

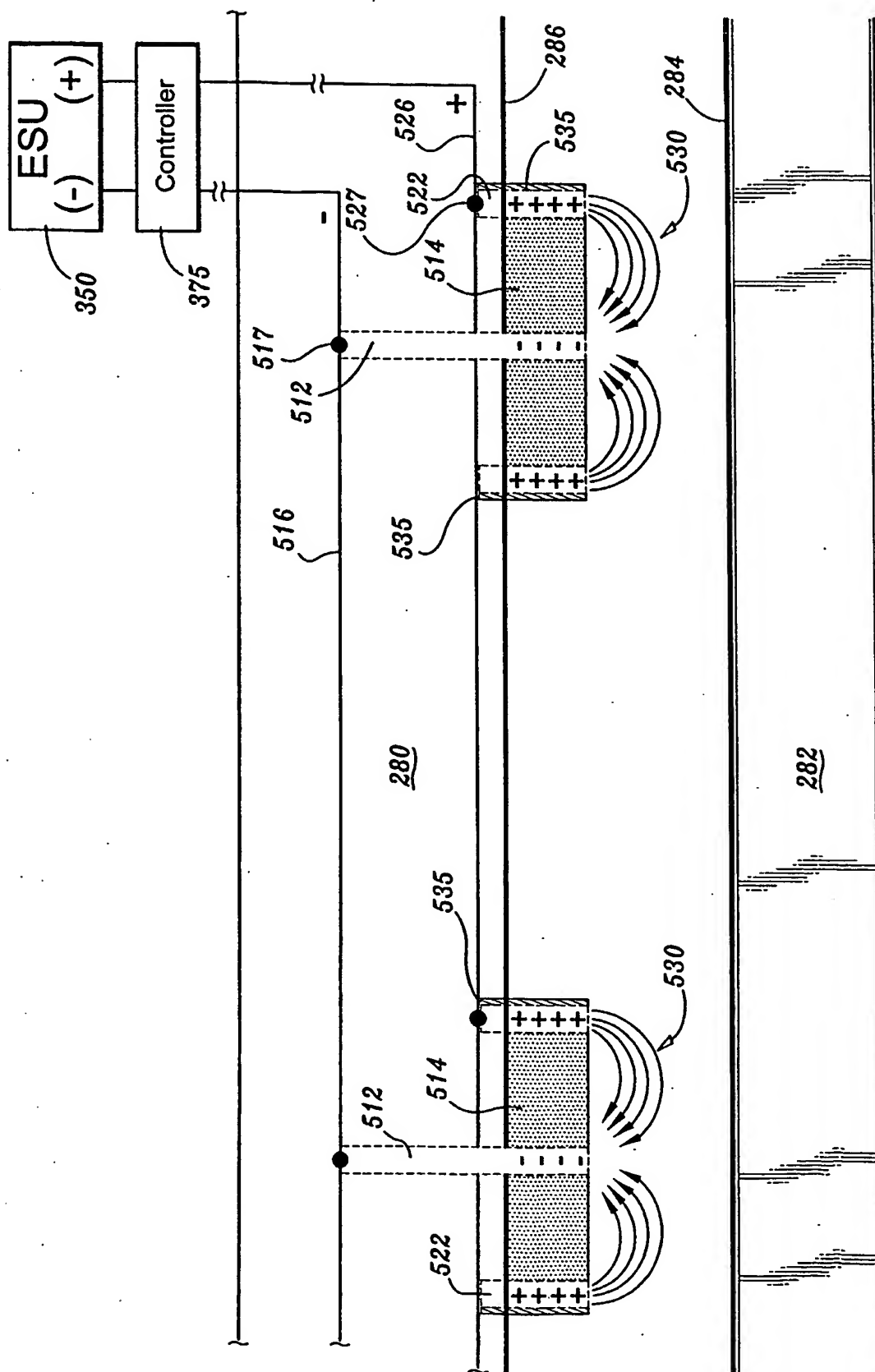


FIG. 4B

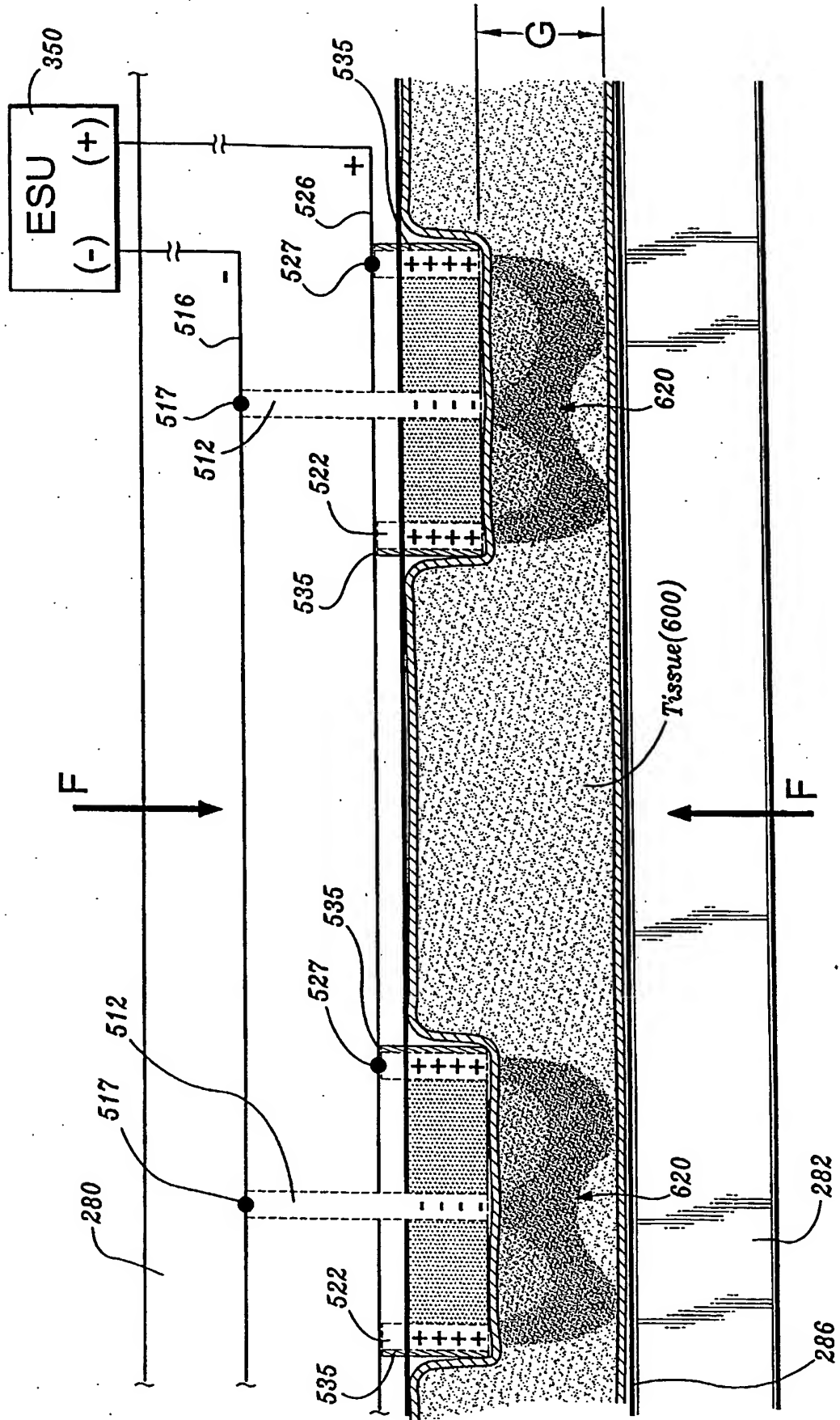


FIG. 4C

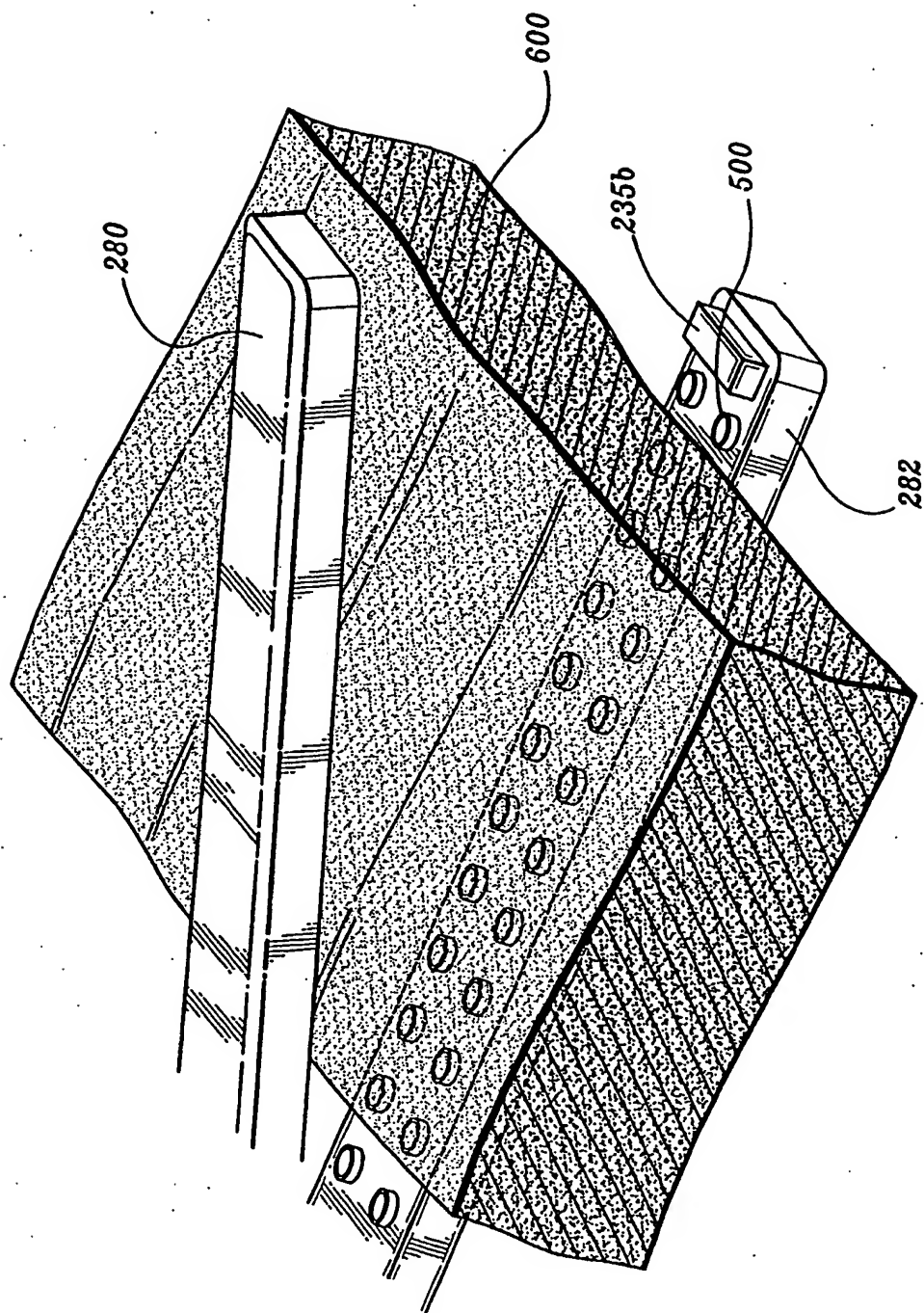


FIG. 5A

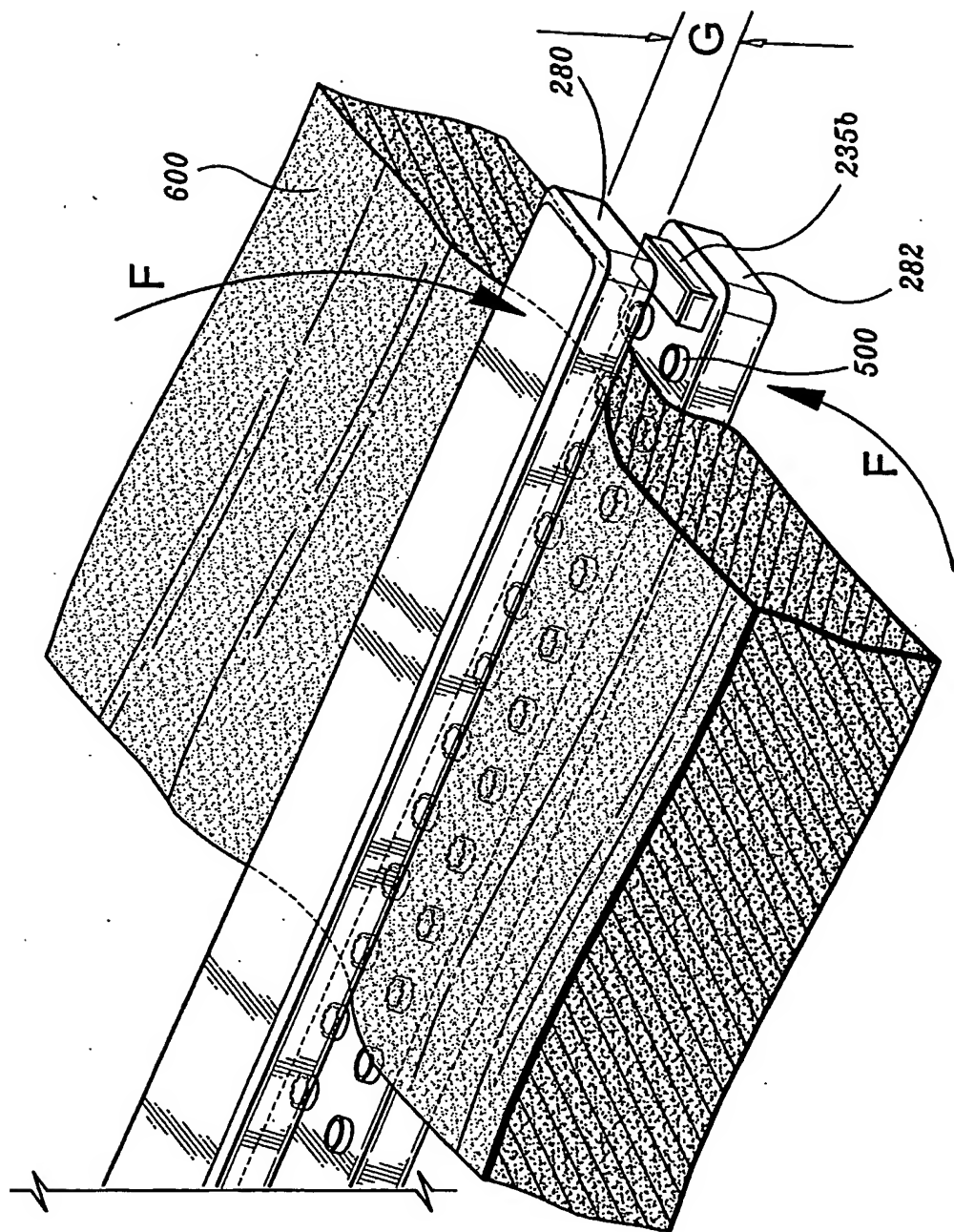


FIG. 5B

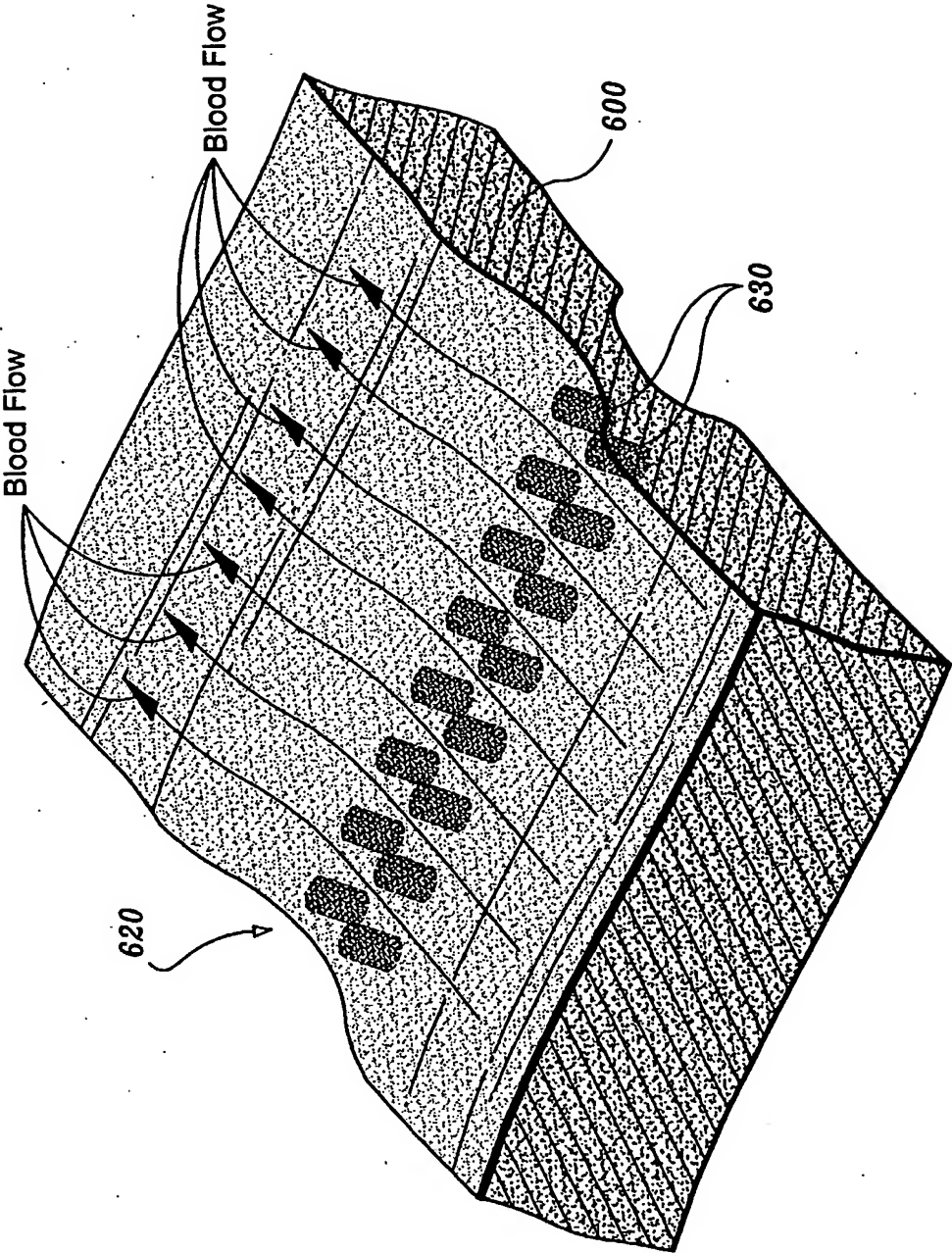


FIG. 5C

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 03/08146

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|-----------------------|
| A | US 5 700 261 A (BRINKERHOFF RONALD J) 23 December 1997 (1997-12-23) summary of invention figure 4 | 1, 16 |
| A | US 6 283 961 B1 (DAVISON TERRY S ET AL) 4 September 2001 (2001-09-04) description fig. 3,4 figures 3,4 | 1, 16 |
| A | US 6 174 310 B1 (KIRWAN JR LAWRENCE T) 16 January 2001 (2001-01-16) figure 3 | 1, 16 |
| A | WO 95 20360 A (VALLEYLAB INC) 3 August 1995 (1995-08-03) page 4, line 25 -page 5, line 10; figure 1 | 1, 16 |
| | -/-- | |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search

1 August 2003

Date of mailing of the international search report

08/08/2003

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/08146

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|-----------------------|
| A | <p>WO 98 31290 A (ELECTROSCOPE INC) 23 July 1998 (1998-07-23) figures 6,8</p> <p>-----</p> | 1,16 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 03/08146

| Patent document cited in search report | | Publication date | Patent family member(s) | Publication date |
|---|----|---------------------|---|--|
| US 5700261 | A | 23-12-1997 | AU 707928 B2 AU 1656197 A CA 2201064 A1 DE 69719581 D1 EP 0797959 A1 JP 10028693 A | 22-07-1999 02-10-1997 29-09-1997 17-04-2003 01-10-1997 03-02-1998 |
| US 6283961 | B1 | 04-09-2001 | US 6277112 B1 US 6159194 A US 5902272 A AU 3296199 A CA 2318891 A1 EP 1061857 A1 JP 2002503508 T WO 9942037 A1 US 6045532 A US 2003014047 A1 US 2003040742 A1 US 6264651 B1 US 6540741 B1 US 6322549 B1 US 6468270 B1 US 6468274 B1 US 2001029370 A1 US 2001056280 A1 AU 9782998 A EP 1018994 A1 JP 2001518352 T WO 9917690 A1 AU 3601797 A EP 0921759 A1 JP 2002514097 T US 2002151885 A1 WO 9803117 A1 US 6179836 B1 US 6264650 B1 US 6575968 B1 US 6105581 A | 21-08-2001 12-12-2000 11-05-1999 06-09-1999 26-08-1999 27-12-2000 05-02-2002 26-08-1999 04-04-2000 16-01-2003 27-02-2003 24-07-2001 01-04-2003 27-11-2001 22-10-2002 22-10-2002 11-10-2001 27-12-2001 27-04-1999 19-07-2000 16-10-2001 15-04-1999 10-02-1998 16-06-1999 14-05-2002 17-10-2002 29-01-1998 30-01-2001 24-07-2001 10-06-2003 22-08-2000 |
| US 6174310 | B1 | 16-01-2001 | NONE | |
| WO 9520360 | A | 03-08-1995 | AU 1076195 A DE 9490471 U1 WO 9520360 A1 JP 2925036 B2 JP 9501859 T | 15-08-1995 26-09-1996 03-08-1995 26-07-1999 25-02-1997 |
| WO 9831290 | A | 23-07-1998 | AU 6274898 A WO 9831290 A1 | 07-08-1998 23-07-1998 |